

# In the United States Court of Federal Claims

## OFFICE OF SPECIAL MASTERS

No. 15-1462V

Filed: February 15, 2017

Not for Publication

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BETSY REDFERN,

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Petitioner,

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v.

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Hepatitis A & B vaccines (“Twinrix”);

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left shoulder pain; osteoarthritis;

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no expert; motion for decision

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dismissing petition granted

SECRETARY OF HEALTH  
AND HUMAN SERVICES,

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Respondent.

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Maximillian J. Muller, Dresher, PA, for petitioner.

Lisa A. Watts, Washington, DC, for respondent.

**MILLMAN, Special Master**

### **DECISION**<sup>1</sup>

On December 3, 2015, petitioner (now 71 years old) filed a petition under the National Childhood Vaccine Injury Act, 42 U.S.C. § 300aa-10-34 (2012), alleging that immediately upon receiving her first Twinrix (hepatitis A and B) vaccination in her left arm on June 30, 2014, she had left shoulder pain. Pet. at ¶ 4. Petitioner alleges she had shoulder injury related to vaccine administration (“SIRVA”). Instead, petitioner has osteoarthritis which her orthopedist Dr. Williams diagnosed. Osteoarthritis<sup>2</sup> is a degenerative disease usually of the elderly.

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<sup>1</sup> Because this unpublished decision contains a reasoned explanation for the special master’s action in this case, the special master intends to post this unpublished decision on the United States Court of Federal Claims’ website, in accordance with the E-Government Act of 2002, 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). Vaccine Rule 18(b) states that all decisions of the special masters will be made available to the public unless they contain trade secrets or commercial or financial information that is privileged and confidential, or medical or similar information whose disclosure would constitute a clearly unwarranted invasion of privacy. When such a decision is filed, petitioner has 14 days to identify and move to redact such information prior to the document’s enclosure. If the special master, upon review, agrees that the identified material fits within the banned categories listed above, the special master shall redact such material from public access.

<sup>2</sup> Osteoarthritis is “a noninflammatory degenerative joint disease seen mainly in older persons, characterized by degeneration of the articular cartilage, hypertrophy of bone at the margins, and changes

Vaccinations do not cause it.

The Federal Circuit in Capizzano v. Secretary of Health and Human Services emphasized that the special masters are to evaluate seriously the opinions of petitioner's treating doctors since "treating physicians are likely to be in the best position to determine whether a logical sequence of cause and effect show[s] that the vaccination was the reason for the injury." 440 F.3d 1317, 1326 (Fed. Cir. 2006); see also Broekelschen v. Sec'y of HHS, 618 F.3d 1339, 1347 (Fed. Cir. 2010); Andreu v. Sec'y of HHS, 569 F.3d 1367, 1375 (Fed. Cir. 2009). No doctors in this case attribute petitioner's osteoarthritis in her left shoulder to her Twinrix vaccination.

On July 21, 2016, the undersigned issued an Order to Show Cause why this case should not be dismissed. Afterward, petitioner filed additional records. On October 18, 2016, petitioner requested time to develop the record. On November 2, 2016, the undersigned held a telephonic status conference and ordered petitioner to file an expert report by January 3, 2017. Petitioner instead decided to move to dismiss.

On February 15, 2017, petitioner filed a Motion for a Decision Dismissing Her Petition. Petitioner states in her motion that she "will be unable to prove that she is entitled to compensation in the Vaccine Program." Mot. at ¶ 2. She also states that "to proceed further would be unreasonable and would waste the resources of the Court, the respondent, and the Vaccine Program." Id. at ¶ 3.

The undersigned **GRANTS** petitioner's motion and **DISMISSES** this case.

### **Medical Records**

#### **Prevaccination**

On April 30, 2012, petitioner went to Boulder Creek Family Medicine where she saw PA Sue A. Griffith. Med. recs. Ex. 8, at 22. Among her concerns was arthritis in her hands, particularly in the distal interphalangeal joint of the fifth finger of her left hand. Id. at 22, 23.

On May 22, 2012, petitioner had a bone mineral density study. Id. at 27. Petitioner weighed 106 pounds with a height of five foot, nine and one-half inches, which was a risk factor for osteoporosis. Id. She had lost one and one-half inches in height. Id.

On June 11, 2012, petitioner went to North Boulder Physical Therapy for an initial evaluation. Med. recs. Ex. 2, at 20. Three weeks earlier, she fell and struck her left kneecap. She reported that she had had numerous falls over the prior two years and was checked for multiple sclerosis, which she did not have. Id. She was concerned regarding her strength and lack of balance. Id.

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in the synovial membrane. It is accompanied by pain, usually after prolonged activity, and stiffness, particularly in the morning or with inactivity." Dorland's Illustrated Medical Dictionary 1344 (32<sup>nd</sup> ed. 2012) (hereinafter, "Dorland's").

### Postvaccination

On June 30, 2014, petitioner received her first Twinrix vaccination in her left arm. Med. recs. Ex. 1, at 4.

On July 28, 2014, petitioner received her second Twinrix vaccination, also in her left arm. Id.

Two and one-half months after receiving her first Twinrix, petitioner saw her personal care physician, Dr. Leto Quarles, at Table Mesa Family Medicine, for her annual medical examination on September 16, 2014. Med. recs. Ex. 8, at 59. Petitioner had a history of bronchiectasis,<sup>3</sup> kidney stones, migraines, being underweight, osteopenia, and chronic lower respiratory insufficiency. Id. She was then about eight months into long-term antibiotic therapy for mycobacterium avium-intracellulare<sup>4</sup> (“MAI”) under treatment at National Jewish Health, and had an appointment the following week for another CT scan and to reassess if she had a component of gastroesophageal reflux disease (“GERD”) and chronic micro-aspiration as well as the lung infection. Id. Dr. Quarles wrote, “In terms of the side effects of the long-term antibiotic use, she remains on twice-daily probiotics and is tolerating them from a GI standpoint. She does get occasional brief twinges of intense and very localized but migratory pain near joints with certain movements, most frequently above the left elbow, which have been attributed to probably low-grade tendinopathy<sup>5</sup> on the antibiotics, and she is tolerating this okay.” Id. On physical examination of petitioner’s left upper extremity, she had no tenderness to palpation. Id. at 63. Petitioner had normal shoulder, elbow, and wrist joint stability. Id. She had normal range of motion. Id. There was no joint crepitus present and no pain with motion. Id.

On September 19, 2014, three days after her annual examination with Dr. Quarles, petitioner saw Dr. William J. Williams, an orthopedist. Med. recs. Ex. 2, at 8. Her chief complaint was left upper arm/shoulder pain for about four months with decreased motion, but no specific injury.<sup>6</sup> Id. Petitioner told Dr. Williams that she had episodes of acute pain in her left

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<sup>3</sup> Bronchiectasis is “chronic dilatation of the bronchi marked by fetid breath and paroxysmal coughing, with the expectoration of mucopurulent matter.” Dorland’s at 252.

<sup>4</sup> Mycobacterium avian-intracellulare complex is “a complex of *Mycobacterium avium* and *M. intracellulare* that causes tuberculosis in birds and swine and is associated with human pulmonary disease . . . .” Dorland’s at 397.

<sup>5</sup> Tendinopathy is “any pathological condition of a tendon . . . .” Dorland’s at 1881. A tendon is “a fibrous cord of connective tissue by which a muscle is attached . . . .” Id. For a discussion of tendinopathy associated with antimicrobial use, see Y. Khaliq and G.G. Zhanel, Fluoroquinolone-Associated Tendinopathy: A Critical Review of the Literature, 36 Clin Infect Dis 1404-10 (2003). <http://cid.oxfordjournals.org>.

<sup>6</sup> Curiously, on September 19, 2014, petitioner told Dr. Williams that she did not have a specific injury to her left upper arm/shoulder, yet in her affidavit, she says when she spoke to Dr. Williams on September 19, 2014, she knew the vaccine had caused her pain. Ex. 9, ¶ 8, at 2. Also curious is that when petitioner saw Dr. Seng on November 12, 2014 for a second opinion about her left shoulder, she told him she could not remember a specific incident related to her shoulder pain but said the pain had an insidious onset three months earlier, or mid-August 2014. Med. recs. Ex. 4, at 21. Furthermore, she told ALTA Physical

biceps muscle.<sup>7</sup> Pain in petitioner's left biceps often occurred when she extended the arm and externally rotated it and when she moved her arm behind her back. Id. Petitioner also had some pain in her left cervical (neck) region. Id. She had a history of some chronic neck pain she thought was related to her doing a lot of travel for her job as an engineer. Id. Petitioner said she lifted luggage regularly and picked up her 40-pound five-year-old grandson. Id.

On physical examination, petitioner did not have any apparent asymmetry between her left versus right biceps or deltoid muscle.<sup>8</sup> Id. Petitioner did not have any tenderness over her biceps or proximal humerus. Id. Her left shoulder was tender at the posterior and anterior glenohumeral joint. Her acromioclavicular ("AC") joint was non-tender. She had slight anterior subacromial tenderness. Petitioner could actively elevate her left arm to 150 degrees and go to 170 degrees with a stretch. Full external rotation was uncomfortable at 60 degrees. Internal rotation was more painful and mildly limited. Getting her wrist to her lower lumbar region caused a fair amount of pain and a negative posterior lift-off test. Petitioner had satisfactory rotator cuff strength on resisted internal and external rotation with the arm at 90 degrees of abduction. Petitioner's impingement tests were mildly positive. Her grip strength in her left upper arm was intact. An x-ray of petitioner's shoulder showed moderate glenohumeral osteoarthritis with subchondral sclerosis and irregularity of the glenoid with a 1 mm. rimming osteophyte.<sup>9</sup> Id. She had an early osteophyte at the inferior head-neck junction. Id. Petitioner had only one or two millimeters of joint space narrowing on the axillary view. Id. Dr. Williams diagnosed petitioner with moderate glenohumeral osteoarthritis with referred left upper arm and shoulder pain. Id. He also diagnosed her with rotator cuff syndrome and neck pain. Id. at 9. Dr. Williams suggested to petitioner that he administer a glenohumeral cortisone injection to relieve petitioner's symptoms, but petitioner did not think her pain was bad enough to have the injection. Id. Instead, she accepted a prescription for physical therapy, and the recommendation of taking Aleve and icing when needed. Dr. Williams suggested petitioner avoid overhead lifting and strengthening as that would likely aggravate her glenohumeral osteoarthritis. Id.

On October 21, 2014, petitioner had a bone mineral densitometry or DEXA performed. Id. at 17. She had lost two inches in height. Her results showed she had osteoporosis. Id.

On November 5, 2014, Dr. Christophe A. Nusser did an MRI of petitioner's left shoulder

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Therapy on November 13, 2014 that the onset of her left shoulder pain was about two months earlier, or September 2014. Med. recs. Ex. 5, at 1. Clearly, petitioner never experienced pain immediately after her June 30, 2014 or she would not have told three different providers that she did not have a specific injury to her left upper arm/shoulder, that her problems with her left arm/shoulder had an insidious onset, and that the onset may have been in August or September 2014.

<sup>7</sup> Twinrix is administered in the deltoid muscle, not in the biceps muscle. Twinrix package insert at 2; [https://www.gsksource.com/pharma\(pdf\)\(revised May 2016\)](https://www.gsksource.com/pharma(pdf)(revised%20May%202016).).

<sup>8</sup> Usually, when an arm or shoulder is painful, a person will not use it as much, causing the biceps or deltoid muscle to atrophy. Since petitioner's left and right biceps and left and right deltoid muscles were symmetrical on September 19, 2014 when Dr. Williams examined her, it follows that she had been using her left arm normally since June 30, 2014, the date of her first Twinrix vaccination.

<sup>9</sup> An osteophyte is "a bony excrescence or osseous outgrowth." Dorland's at 1348.

without contrast to evaluate her for labral or rotator cuff tear. Id. at 15. Dr. Nusser found minimal degenerative change in petitioner's acromioclavicular joint. There was a mild subacromial-deltoid fluid collection. Petitioner had mild abnormal signal intensity in her distal supraspinatus tendon with mild bursal surface fraying and attenuation in the distal of 1 cm. She had mild edema at the musculotendinous junction of the infraspinatus. Petitioner had mild abnormal signal intensity in the intraarticular portion of her long head biceps tendon and attenuation at the biceps anchor. She had degenerative signal and fraying in her superior labrum at the biceps anchor and fraying or partial tear at the posterior superior labrum with a diminutive appearance. There was mild cartilage signal abnormality and thinning in the posterior superior glenoid. The inferior capsule was thickened with pericapsular edema. Id.

On November 12, 2014, petitioner saw Dr. Khemarin R. Seng, an orthopedist, complaining of a left frozen shoulder. Med. recs. Ex. 4, at 21. She said she had an insidious onset three months earlier, putting onset in mid-August 2014 six weeks after her first Twinrix vaccination. In 2013, petitioner had flown 10 million miles. Id. She said she slept in odd positions. Id. She carried luggage awkwardly. Id. In addition, petitioner could not remember a specific incident that could have injured her left shoulder. Id. She saw Dr. Williams and received a posterior shoulder injection, which did not help. She underwent an MRI which showed multiple tears. She went to Dr. Seng for a second opinion. Id. Dr. Seng gave petitioner an anterior shoulder glenohumeral joint injection. Id. He prescribed physical therapy three times a week for four weeks. Id.

On November 17, 2014, petitioner went to ALTA Physical Therapy with a diagnosis of adhesive capsulitis which had an insidious onset a couple of months ago (or September 2014). Med. recs. Ex. 5, at 1.

On December 15, 2014, petitioner saw Dr. Seng to discuss left shoulder surgery scheduled for January 5, 2015. Med. recs. Ex. 4, at 18. Her pain was better, but her limited motion was the same. Physical therapy improved her motion, but then it reverted to its limited state. Id. On physical examination, petitioner did not have any significant pain. Id. Her MRI of the left shoulder showed mild tendinopathy and mild arthritis. Id. Petitioner said she wanted to proceed with scope, cleanup, and capsular release with manipulation. Id.

On January 20, 2015, petitioner saw Dr. Seng. Id. at 16. Petitioner said her left shoulder felt okay, the pain was minimal, but her shoulder motion had not improved. Id. She wanted to postpone surgery until summer to see if her motion improved. Id.

On February 17, 2015, petitioner saw Dr. Seng. Id. at 13. She said her left shoulder pain was better but her shoulder motion had not improved. Id. Petitioner said she was tired of her current shoulder motion and had exhausted conservative measures. Id.

On March 9, 2015, petitioner had surgery on her left shoulder for adhesive capsulitis, impingement, rotator cuff tear, and synovitis. Id. at 28. As part of the surgery, Dr. Seng removed a large distal clavicle osteophyte inferiorly hanging. Id. at 29.

On March 16, 2015, petitioner saw Dr. Seng for a post-op visit. Id. at 11. Dr. Seng said petitioner's shoulder looked great. Id. She had minimal pain but more pain with internal rotation. Id.

On April 14, 2015, petitioner saw Dr. Seng for a re-check of her left shoulder. Id. at 9. Her left shoulder was better than before, but petitioner had not kept up with stretching. Id. Dr. Seng requested she refocus on motion and showed her some physical exercise. Id.

### **DISCUSSION**

To satisfy her burden of proving causation in fact, petitioner must prove by preponderant evidence: "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." Althen v. Sec'y of HHS, 418 F.3d 1274, 1278 (Fed. Cir. 2005). In Althen, the Federal Circuit quoted its opinion in Grant v. Secretary of Health and Human Services, 956 F.2d 1144, 1148 (Fed. Cir. 1992):

A persuasive medical theory is demonstrated by "proof of a logical sequence of cause of and effect showing that the vaccination was the reason for the injury [,]" the logical sequence being supported by a "reputable medical or scientific explanation[,]" i.e., "evidence in the form of scientific studies or expert medical testimony[.]"

418 F.3d at 1278.

Without more, "evidence showing an absence of other causes does not meet petitioner's affirmative duty to show actual or legal causation." Grant, 956 F.2d at 1149. Mere temporal association is not sufficient to prove causation in fact. Id. at 1148.

Petitioner must show not only that but for her Twinrix vaccination, she would not have osteoarthritis in her left shoulder, but also that her Twinrix vaccination was a substantial factor in causing her to develop osteoarthritis in her left shoulder. Shyface v. Sec'y of HHS, 165 F.3d 1344, 1352 (Fed. Cir. 1999).

There is no evidence in these medical records that petitioner reacted to the Twinrix vaccination she received on June 30, 2015. The Vaccine Act, § 300aa-13(a)(1), prohibits the undersigned from ruling for petitioner based solely on her allegations unsubstantiated by medical records or medical opinion. None of petitioner's medical records supports her allegations. Instead, they attribute her left shoulder problem to osteoarthritis. Petitioner has not filed a medical expert report in support of her allegations.

On February 15, 2017, petitioner filed a Motion for a Decision Dismissing the Petition. The undersigned **GRANTS** petitioner's Motion for a Decision Dismissing the Petition and

**DISMISSES** this case.

**CONCLUSION**

This petition is **DISMISSED**. In the absence of a motion for review filed pursuant to RCFC Appendix B, the clerk of the court is directed to enter judgment herewith.<sup>10</sup>

**IT IS SO ORDERED.**

Dated: February 15, 2017

/s/ Laura D. Millman  
Laura D. Millman  
Special Master

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<sup>10</sup> Pursuant to Vaccine Rule 11(a), entry of judgment can be expedited by each party, either separately or jointly filing a notice renouncing the right to seek review.